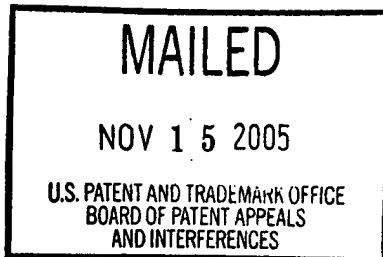


The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BRIAN S. KELLEHER, JAMES F. MARINO, CORBETT W. STONE,
ROBIN H. VAUGHN and JEFFREY H. OWENS



Appeal No. 2005-1834
Application No. 09/722,070

ON BRIEF

Before FRANKFORT, McQUADE, and NASE, Administrative Patent Judges.
McQUADE, Administrative Patent Judge.

DECISION ON APPEAL

Brian S. Kelleher et al. appeal from the final rejection mailed October 21, 2003. The appeal involves claims 15, 16, 22 through 26 and 30 through 40.

THE INVENTION

The invention relates to "systems for detecting the presence of nerves during surgical procedures" (specification, page 1). Representative claim 15 reads as follows:

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15. A method for detecting the presence of a nerve adjacent the distal end of at least one probe or surgical tool, comprising:
(a) emitting a stimulus pulse from an electrode disposed on a probe or surgical tool as said probe or tool is introduced towards the patient's spine from a generally lateral direction;
(b) detecting neuro-muscular responses to the stimulus pulse in at least one of a plurality of spinal nerves; and
(c) concluding that the electrode disposed on the probe or surgical tool is positioned adjacent to a first spinal nerve when the neuro-muscular response detected in the first spinal nerve is detected as a current intensity level less than or equal to a neuro-muscular response signifying close proximity to the first spinal nerve.

THE PRIOR ART

The references relied on by the examiner to support the final rejection are:

Raymond et al. (Raymond '153)	5,284,153	Feb. 08, 1994
Raymond et al. (Raymond '154)	5,284,154	Feb. 08, 1994
Raymond et al. (Raymond '331)	5,775,331	Jul. 07, 1998
Hadzic et al. (Hadzic)	5,830,151	Nov. 03, 1998
Feler et al. (Feler)	6,027,456	Feb. 22, 2000

THE REJECTIONS

Claims 15, 16, 22 through 26, 30, 31 and 33 through 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Raymond '331 in view of Feler.

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Claims 15, 16, 22 through 26, 30, 31 and 33 through 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either Raymond '153 or Raymond '154 in view of Feler.

Claims 15, 16, 22 through 26, 30, 32, 33, 35 and 40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hadzic in view of Feler.

Attention is directed to the brief filed July 2, 2004 and answer mailed August 24, 2004 for the respective positions of the appellants and examiner regarding the merits of these rejections.¹

¹ In a paper filed October 6, 2003, the appellants gave an express instruction to cancel claim 40 (see page 1), and then reproduced and discussed the claim as if it were still pending (see pages 4 through 6). The examiner treated claim 40 in the final rejection as canceled, but included it in the above rejections in the answer in apparent response to the appellants' statement in the brief (see page 2) that claim 40 was pending and inadvertently omitted from the final rejection. For purposes of the appeal, we assume that claim 40 is pending and rejected as shown above. In the event of further prosecution, steps should be taken to clarify the record as to the status of this claim.

DISCUSSION

I. The examiner's rejections

We shall not sustain any of the standing 35 U.S.C. § 103(a) rejections. For the reasons expressed below, the scope of claims 15, 16, 22 through 26 and 30 through 40 is unclear. Thus, the standing prior art rejections must fall since they are necessarily based on speculative assumption as to the meaning of the claims. See In re Steele, 305 F.2d 859, 862-63, 134 USPQ 292, 295 (CCPA 1962). It should be understood, however, that our decision in this regard rests solely on the indefiniteness of the claimed subject matter, and does not reflect on the adequacy of the prior art evidence applied in support of the rejections.²

²As framed and argued by the appellants (see pages 4 through 10 in the brief), the dispositive issue with respect to the merits of the examiner's 35 U.S.C. § 103(a) rejections would have been whether the references applied to support each rejection teach or suggest a method responding to the limitation in independent claim 15 requiring the probe or tool to be introduced towards the patient's spine from a generally lateral direction. In an effort to expedite any further prosecution resulting from this decision, we would note that Feler appears to suggest, if not actually teach, introduction of a probe towards a patient's spine from a generally lateral direction at, for example, column 3, lines 38 through 42, column 4, lines 59 through 61, and column 7, line 65, through column 8, line 1, and that Raymond '153, Raymond '154 and Hadzic ostensibly show such lateral introduction in Figure 1 of these references.

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II. New rejection

The following rejection is entered pursuant to 37 CFR
§ 41.50(b).

Claims 15, 16, 22 through 26 and 30 through 40 are rejected
under 35 U.S.C. § 112, second paragraph, as failing to
particularly point out and distinctly claim the subject matter
the appellants regard as the invention.

The second paragraph of 35 U.S.C. § 112 requires claims to
set out and circumscribe a particular area with a reasonable
degree of precision and particularity. In re Johnson, 558 F.2d
1008, 1015, 194 USPQ 187, 193 (CCPA 1977). In determining
whether this standard is met, the definiteness of the language
employed in the claims must be analyzed, not in a vacuum, but
always in light of the teachings of the prior art and of the
particular application disclosure as it would be interpreted by
one possessing the ordinary level of skill in the pertinent art.
Id.

The following passages from the appellants' specification fairly summarize the nerve detecting method disclosed by the appellants:

In a first aspect, the present invention provides a system for detecting the presence of a nerve near a surgical tool or probe, based upon the current intensity level of a stimulus pulse applied to the surgical tool or probe. When a measurable neuro-muscular (EMG) response is detected from a stimulus pulse having a current intensity level at or below a pre-determined onset level, the nerve is considered to be near the tool or probe and thus, detected.

In an optional second aspect of the invention, the onset level (i.e.: the stimulus current level at which a neuro-muscular response is detected for a particular nerve) may be based on EMG responses measured for a probe at a predetermined location relative to the nerve. Specifically, onset levels may first be measured for each of a plurality of spinal nerves, (yielding an initial "baseline" set of neuro-muscular response onset threshold levels), which are then used in the first (nerve detection) aspect of the invention. Therefore, in accordance with this optional second aspect of the invention, a system for determining relative neuro-muscular onset values (i.e.: EMG response thresholds), for a plurality of spinal nerves is also provided. Accordingly, the pre-determined onset level may be compared to the current level required to generate a measurable EMG response for a tool or probe being advanced toward one or more nerves of interest.

In alternate aspects, however, the neuro-muscular onset values which are used to accomplish the first (nerve detection) aspect of the invention are not measured for each of the patient's plurality of spinal nerves. Rather, pre-determined levels of current intensity (below which neuro-muscular responses are detected in accordance with the first aspect of the invention) can instead be directly pre-set into the

system. Such levels preferably correspond to specific expected or desired onset threshold values, which may have been determined beforehand by experimentation on other patients [page 2, line 24, through page 3, line 14];

In the first (nerve sensing) aspect of the invention, the present nerve-detection system comprises an electrode or electrodes positioned on the distal end of the surgical tool or probe, with an electromyographic system used to detect whether a spinal nerve is positioned adjacent to the surgical tool or probe. A conclusion is made that the surgical tool or probe is positioned adjacent to a spinal nerve when a neuro-muscular (e.g.: EMG) response to a stimulus pulse emitted by the electrode or electrodes on the surgical tool or probe is detected (at a distant myotome location, such as on the patient's legs) at or below certain neuro-muscular response onset values (i.e.: pre-determined current intensity levels) for each of the plurality of spinal nerves [page 4, lines 1 through 9];

and

. . . [T]he present system involves applying a signal with a current level to a probe near a nerve and determining whether an electromyographic "EMG" (i.e.: neuro-muscular) response for a muscle coupled to the nerve is present.

In preferred aspects, the present system applies a signal with a known current level (mA) to a "probe" (which could be midline probe, a cannula, a needle, etc.) Depending on the current level, distance to the nerve, and health of the nerve, an EMG may be detected in a muscle coupled to the nerve. In accordance with preferred aspects, an EMG response is determined to have been detected when the peak-to-peak response of the EMG signal is greater than some level (mVolts). In other words, an EMG response is determined to have been detected when the stimulus current level generates an EMG having a peak-to-peak value greater than a

pre-determined level (for example, 60mV or 80mV in spinal nerve applications.) [page 10, lines 7 through 18].

Considered in light of this disclosure, steps (b) and (c) in independent claim 15 do not make sense. More particularly, step (b) requires the detection of neuro-muscular responses "in" at least one of a plurality of spinal nerves. The underlying disclosure, on the other hand, makes it quite clear that the neuro-muscular responses are detected in muscles coupled to the nerves at distant myotome locations rather than in the nerves themselves. Step (c) refers back to the detection of a neuro-muscular response "in" a spinal nerve, and further sets forth that such neuro-muscular response is detected "as a current intensity level less than or equal to a neuro-muscular response signifying close proximity to the first spinal nerve." In contrast, the underlying disclosure indicates that the neuro-muscular response is detected as a potential (mVolts) rather than a current intensity level (mA), and that close proximity to the nerve is signified when the current intensity level of the stimulus pulse, not the neuro-muscular response, is less than or equal to a baseline or predetermined current intensity level. Given these multiple inconsistencies, independent claim

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15 and dependent claims 16, 22 through 26 and 30 through 40 are indefinite.

SUMMARY

The decision of the examiner to reject claims 15, 16, 22 through 26 and 30 through 40 is reversed, and a new rejection of these claims is entered pursuant to 37 CFR § 41.50(b).

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) which provides that "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

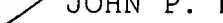
(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .


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(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED; 37 CFR § 41.50(b).

Charles E. Frankfort
CHARLES E. FRANKFORT
Administrative Patent Judge


JOHN P. McQUADE
Administrative Patent Judge


JEFFREY V. NASE
Administrative Patent Judge

BOARD OF PATENT
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